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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/601,513 09/25/00 THALLER

M 1303-102

HM12/1101

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EXAMINER

FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

11/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/601,513

Applicant(s)

THALLER ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2001 (Paper No 7) has been received and entered. Claims 1-14 were cancelled and new claims 15-25 were added. Consequently claims 15-25 are pending in the instant application. All grounds of rejection in the previous Office Action are withdrawn in view of the cancellation of claims 1-14.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is directed to *Staphylococcal* strain DSMZ No. 11942. *Staphylococcus* which encompasses DSMZ No. 11942 would be found naturally in the environment if the bacterial strain is not isolated. Therefore DSMZ No. 11942 does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere

Art Unit: 1645

purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated *Staphylococcus aureus* strain DSMZ No. 11942..."

Claim Rejections - 35 USC § 112

2. Claims 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "other biological fluid samples antibodies". One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, what types of antibodies obtained from which other biological fluid(s) are encompassed by the claimed invention? Without a clear definition as to which antibodies and which biological fluid(s) are encompassed by the claimed invention, one of skill in the art would be unable to replicate the claims.

Art Unit: 1645

3. The claims are further vague and indefinite in the recitation of "modified" HHW medium. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, how has the HHW been modified? Without a clear definition as to how the HHW medium has been modified, one of skill in the art would be unable to replicate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1645

4. Claims 15-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Karamanos* and *Hussain et al.* in view of *McKenney et al.*

The claims are drawn to a method of detecting a *Staphylococcal* polysaccharide in a biological sample comprising culturing a staphylococcal strain in a defined medium, homogenizing, centrifuging, desalting, and freezing the supernatant to obtain the polysaccharide.

Karamanos et al. (Archives of Biochemistry and Biophysics Vol. 342 1997 pp.389-395) disclose a method of detecting Staphylococcal antibodies in blood serum. *Karamanos et al.* further disclose a method of detecting Staphylococcal antibodies which react with the polysaccharide produced by *Staphylococcus epidermis* (See Abstract). *Karamanos et al.* further disclose use of *Staphylococcal* antibodies in an immunochemical assay (See Material and Methods Section; Immunological Methods).

Karamanos et al. does not teach of a method of making a *Staphylococcal* polysaccharide comprising culturing a staphylococcal strain in a defined medium, homogenizing, centrifuging, desalting, and freezing the supernatant to obtain the polysaccharide.

Hussain et al. (Journal of Medical Microbiology Vol. 34 1991 pp.143-47) teach of a chemically defined medium for slime production from *Staphylococcus*.

McKenney et al. (Infection and Immunity Vol. 66(10) 1998 pp.4711-20) teach of a method of making a *Staphylococcal* polysaccharide comprising homogenizing, centrifuging, desalting, and freezing the supernatant of a *Staphylococcal* strain to obtain the polysaccharide (See Material and Methods Section; Purification of Polysaccharide).

Art Unit: 1645

Given that 1) Karamanos *et al.* has taught of a method of detecting Staphylococcal antibodies in blood serum which react with the polysaccharide produced by *Staphylococcus epidermis* and that 2) Hussain *et al.* has taught of a chemically defined medium for slime production from *Staphylococcus* and that 3) McKenney *et al.* has taught of a method of making a *Staphylococcal* polysaccharide it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect a *Staphylococcal* polysaccharide in a biological sample. One would have been motivated to detect such a polysaccharide in view of the teachings of Karamanos and McKenney *et al.* that the polysaccharide of *Staphylococcus* is involved in prosthetic infections.

5. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.* in view of Fisher *et al.*

The claims are drawn to a method of detecting Staphylococcal antibodies reacting with a polysaccharide in a biological fluid.

Davis *et al.* (Patent 992132) disclose several methods for preparing polysaccharides produced by *Staphylococcus*.

Although the reference appears to disclose the same product claimed by applicants, the reference does not disclose the products produced by the claimed process. However the purification of production of a product by a particular process does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

Art Unit: 1645

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Therefore even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art.

See In re King, 107 F. 2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F. 2d 599, 601, 38 USPQ 143-145 (CCPA 1938); In re Bergy, 563 F. 2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) vacated 438 US 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

Fisher *et al.* (WO 96/09321) disclose a method for identifying, making and isolating immunoglobulin and antigen useful for preventing, diagnosing, and treating Staphylococcal infection. Fisher *et al.* further disclose a method for detecting IgG and IgM antibodies in a biological fluid (See especially Method of Isolating Immunoglobulin p.16 and Example 1 page 24). Fisher *et al.* further disclose a method for detecting Staphylococcal antibodies in combination with additives which may be used in diagnostic tests (i.e. diagnostic kits).

Given that 1) Davis *et al.* has taught of several methods for isolating polysaccharides produced by *Staphylococcus* and that 2) Fisher *et al.* has taught of a method for identifying, making and isolating immunoglobulin and antigen useful for preventing, diagnosing, and treating Staphylococcal infection it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect Staphylococcal antibodies reacting with a polysaccharide in a biological fluid. One

Art Unit: 1645

would have been motivated to detect *Staphylococcal* antibodies reacting with a polysaccharide in a biological fluid in view of the teachings of Fisher *et al.* that *Staphylococcal* infections have become a cause of human morbidity in hospital patients.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

October 26, 2001


MARK NAVARRO
PRIMARY EXAMINER